



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances Application: Catalent CTS, LLC

[Docket No. DEA-392]

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.34(a) on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESS: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION:

The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR

0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (“Deputy Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on May 6, 2016, Catalent CTS., LLC., 10245 Hickman Mills Drive, Kansas City, Missouri 64137 applied to be registered as an importer of the following basic classes of controlled substances:

| Controlled Substance | | Schedule |
|-----------------------------|------|-----------------|
| Gamma Hydroxybutyric Acid | 2010 | I |
| Marihuana | 7360 | I |

The company plans to import finished dosage unit products containing gamma-hydroxybutyric acid and cannabis extracts for clinical trial studies.

These cannabis extracts compounds are listed under drug code 7360. No other activity for this drug code is authorized for this registration. Approval of permit applications will occur only when the registrant’s business activity is consistent with what is authorized under to 21 U.S.C. 952(a)(2). Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Dated: September 19, 2016.

Louis J. Milione,

Deputy Assistant Administrator.

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